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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/402,636	04/26/00	MASCAX	R 17620-9277

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EXAMINER

HUYNH, P

ART UNIT

PAPER NUMBER

1644

7

DATE MAILED:

12/13/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/402,636

Applicant(s)

MASCAX ET AL.

Examiner

"Neon".Phuong Huynh

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE One MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claims 1-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121 and 372:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this Action, to elect a single invention to which the claims must be restricted:

- I. Claims 1-22, drawn to a conjugate comprising a Vitamin D moiety and a target molecule moiety having an affinity for a tissue of interest.
- II. Claims 23-27, drawn to a method of site-specific delivery of a vitamin D to a tissue of interest of a patient having a bone or proliferative disease.
- III. Claims 28-31, drawn to an anti-proliferative composition having a conjugate of formula of $(I) (D)_m * (T)_n$.
- IV. Claims 32-33, drawn to a conjugate having the formula of $[(T)_n - (G')_f]_g * [(G'')_n - (D)_m]_r$.
- V. Claims 34-40 drawn to an anti-proliferative composition, a conjugate having the formula of $(D)_m * (T)_n * (A)_p$ and method of treating bone or proliferative disease in a human subject.

The inventions listed as Groups I-V above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Consistent with the International Search Report, the Invention of Group I-V was to have no special technical feature that defined the contribution over the prior art of U.S. Pat. 5,691,328, and U.S. Pat 5,232,836.

Peterson *et al.* ('328) teach conjugates of Vitamin D compounds and a method of treating hyperproliferative disorder. (See entire document, in particular, column 4, paragraph Utility).

Bouillon *et al.* ('836) teach Vitamin D derivative and the therapeutic applications of Vitamin D3 derivatives. (See entire document). Therefore the invention of Group I has been previously described.

Since Applicant's Inventions do not contribute a special technical feature when viewed over the prior art, they do not have a single general inventive concept and lack unity of invention.

3. This application contains claims directed to the following distinct species of the claimed Invention of Group I, II, III, IV or V wherein the targeting molecule moiety having affinity for bone, skin, prostate or tumor as disclosed on page 9 of the specification.

These species are distinct because the structures of different targeting molecule moieties, therapeutic/cytotoxic agent differ with respect to their structure and physiochemical properties, targeting different tissues and different specific diseases differ with respect to their etiologies, and therapeutic endpoints. Therefore, they are patentably distinct.

In addition to electing an Invention from Groups I-V and a species from target molecule moiety, bone-seeking agent, therapeutic/cytotoxic agent, applicant must elect an ultimate species from the following:

Wherein the specific target molecule moiety as disclosed in the specification on page 9 is:

- A) Bisphosphonate moiety for bone,
- B) Dehydroepiandrosterone for prostate,
- C) Divalent metal ion linked to vitamin D moiety via an amide linkage for skin, or
- D) Antibody for tumor.

Wherein the specific bone-seeking agent as recited in claims 31 is:

- A) Bisphosphonate,
- B) Tetracycline,
- C) Polymalonate or
- D) Dehydroepiandrosterone.

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Wherein the specific therapeutic/cytotoxic agent as recited in claims 17, 18, 34 is:

- A) Estrogen or their equivalents,
- B) Anti-estrogens,
- C) Calcitonin,
- D) Bisphosphonates,
- E) Calcium supplements,
- F) Cobalamin,
- G) Pertussis toxin,
- H) Boron,
- I) Dehydroepiandrosterone,
- J) TGF β ,
- K) Activin,
- L) Bone morphogenic protein,
- M) Estromustene phosphate,
- N) Prednimustine,
- O) Cisplatin,
- P) S-fluorouracil,
- Q) Melphalan,
- R) Hydroxyurea,
- S) Mitomycin,
- T) Idarubicin,
- U) Methotrexate,
- V) Adriamycin, or
- W) Daunomycin.

In addition to electing an Invention from Groups I-V, a species from specific target molecule moiety, a specific therapeutic agent, and a specific bone-seeking agent, applicant must elect an ultimate species from the following.

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If Group I, II, III, IV or V is elected, applicant is further required under 35 U.S.C. 121 to

- A) Select a specific target molecule moiety as recited in claims 1, 20, 23, 28, 32 and 34, for example,
- B) Select a specific therapeutic agent as recited in claim 17, 18, 19, 23, 34, 35 and 40, for example, and
- C) Select a specific bone-seeking agent as recited in 30, 31, 36 and 38, for example.

If Group II, III or V is elected, applicant is further required under 35 U.S.C. 121 to select a specific disease as disclosed on page 5 of the specification wherein the specific disease is:

- A) Bone
- B) Leukemia,
- C) Prostate cancer, or
- D) Skin.

These species are distinct because the specific diseases differ with respect to their tissue specificity, etiologies, and therapeutic endpoints. Therefore, they are patentably distinct.

4. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 23, 28, 30, 31, 32, 34, 35, 36, 37, 38 and 40 are generic.

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5. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).
8. A telephone call to request an oral election was not made due to the complexity of the restriction.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 8:00 am to 5:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.
10. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phuong N. Huynh, Ph.D.
Patent Examiner
Technology Center 1600
December 4, 2000

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12/16/00